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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/550,026

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EXAMINER

LUCAS, ZACHARIAH

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/550,026	Applicant(s) MOREIN ET AL.	
	Examiner Zachariah Lucas	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 3, 11, 16, 17, and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-10, 12-15, 18 and 20-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-23 are pending in the application.
2. In the prior action, mailed on July 28, 2008, claims 1-19 were pending in the application; with claims 3, 11, 16, 17, and 19 withdrawn from consideration; and claims 1, 2, 4-10, 12-15, and 18 under consideration are rejected.
3. In the Response of October 28, 2008, the Applicant amended claims 1, 8, and 14; and added new claims 20-23.
4. Claims 1, 2, 4-10, 12-15, 18, and 20-23 are under consideration.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. **(Prior Rejection- Maintained in part)** Claims 1, 2, 4-8, 14, and 18 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is withdrawn from claims 1, 2, 4-7, and 18; but is maintained over claims 8 and 14, and extended to new claims 22 and 23

The claims were previously rejection on two grounds. One of these grounds is withdrawn, the other is maintained. In addition, a new ground of rejection is made regarding new claims 22 and 23.

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The first ground of rejection was a rejection of claims 1, 2, 4-8, and 18 as indefinite because it was not clear if the claim was implicitly requiring that the iscom particle be combined with the antigen composition, or if the claim is merely requiring that an iscom be used as an adjuvant without specifically requiring the combination of the iscom and the antigen prior to administration. In view of the amendment of the claims, this portion of the rejection is withdrawn.

The second ground of rejection applies to claims 8 and 14. These claims are rejected because it is not clear what is meant by reference to “subfragment A and subfragment C or Quillaja saponin Fraction A.” The claims have been amended to refer to Fractions A and C of Quillaja saponin Fraction A. The amendment is not found sufficient to overcome the rejection. As was indicated in the prior action, the application and art refer to Fractions A and C of the “homogenous” fraction Quil A from the tree *Quillaja saponaria* Molina. However, there is nothing in the application or art to indicate what is meant by reference to Fractions A or C of Quillaja saponin Fraction A. It is therefore unclear if the term Quillaja saponin Fraction A is intended to refer to the Quil A homogenous fraction referred to in the art and the prior action, or if the terms Fraction A and Fraction C of Quillaja saponin Fraction A are intended to describe some subfraction of the Fraction A of Quil A described in the prior art.

Moreover, the rejection is extended to new claims 22 and 23 as it is not clear what is meant by reference to “different Fractions of Quillaja saponin Fraction A” for the reasons indicated above.

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As in the prior action, for the purposes of this action, the claims will be treated as reading on the use of fractions (such as Fractions A and C) from the homogenous mixture of Quil A, unless otherwise indicated.

This portion of the rejection is therefore maintained.

In addition, new claims 22 and 23 are additionally rejected on the basis that it is not clear what is meant by the claim language “wherein a plurality of the iscom particles comprise different Fractions of Quillaja saponin Fraction A.” It is not clear from the claim language if the claim is reading on embodiments wherein the plurality of iscoms each have the same saponins which is made up of different fractions of Quil A (e.g. a combination of Fractions A and C), or if the claims are drawn to embodiments wherein the plurality of iscom particles comprise a plurality of iscom particle populations, each comprising a different Fraction of Quil A from the other iscom populations.

Clarification of the claim language is required.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. **(Prior Rejection- Maintained)** Claims 1, 2, 6, 9, 10, and 15 were rejected under 35 U.S.C. 102(b) as being anticipated by Wechter et al. (U.S. 6,177,081). The rejection is extended

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to new claim 21, which reads on substantially similar subject matter as previously rejected claim 6.

Applicant traverses the rejection on the basis of the assertion that the teachings of Wechter “inevitable involves production steps that will kill the micro-organisms.” The argument is not found persuasive.

It is noted that the Applicant has provided no evidence in support of these “inevitable” production steps. Thus, the argument in traversal is only than, an argument by the Applicant’s attorney. Such arguments are not sufficient where evidence is required. See e.g., MPEP 2145 I.

Moreover, the arguments are not consistent with the teachings of the reference, which specifically indicates that “Live attenuated viruses can also be incorporated into immunostimulating complexes (ISCOM) for use as a vaccine using methods well known in the art.” The reference specifically indicates that the live viruses can be incorporated into the ISCOMs, and nowhere indicates that the end result would be an inactivated (killed) virus. Rather, the reference teaches the use of inactivated viruses as an alternative to the use of live viruses. See e.g., column 8 lines 50-65.

For the reasons above, and the reasons of record, the rejection is maintained.

9. **(Prior Rejection- Withdrawn)** Claims 1, 2, 6, 7, 8, and 18 were rejected under 35 U.S.C. 102(b) as being anticipated by Iosef et al. (Vaccine 20:1740-53). In view of the amendments to the claims, the rejection is withdrawn.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. **(Prior Rejection- Maintained)** Claims 1, 2, 5-10, and 13-15 were rejected under 35 U.S.C. 103(a) as being unpatentable over Wechter et al. (U.S. 6,177,081) in view of Morein et al. (U.S. 5,679,354).

The rejection is extended to new claims 20 and 21, which include substantially the same limitations as previously rejected claims 5 and 6. The rejection is also extended to new claims 22 and 23, assuming that the claims read on embodiments wherein a single population (i.e. a plurality) of iscoms comprises more than one Fraction of Quil A (thereby inherently reading on the use of Quil A as the glycoside). On this basis, the rejection is extended to these claims on the same basis that the rejection was applied to claims 7, 8, 13, and 14 in the prior action.

The Applicant traverses this rejection on the same grounds as asserted with respect to the anticipation rejection over Wechter above. The arguments are not found persuasive for the reasons indicated above. The rejection is therefore maintained for the reasons of record, and the reasons above.

12. **(Prior Rejection- Maintained)** Claims 7, 8, 13, and 14 were rejected under 35 U.S.C. 103(a) as being unpatentable over Wechter in view of Morein as applied above, and

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further in view of Cox et al. (WO 96/11711). The rejection is extended to new claims 22 and 23, regardless of which interpretation of the claims as describe above is applied.

As was indicated in the prior action, Cox indicates that iscoms may include either of the glycosides of Fractions A or C of Quil A. Because the reference indicates that both Fractions are equally useful, it would have been obvious to those of ordinary skill in the art to have used either, or a combination of the two, for the formation of iscoms. Among the obvious embodiments from the reference would be the use of different populations of iscoms, each based upon the use of a different Fraction of Quil A, or on the combination of both Fractions in a single population of iscoms.

The Applicant traverses this rejection on the same grounds as asserted with respect to the anticipation rejection over Wechter above. The arguments are not found persuasive for the reasons indicated above. The rejection is therefore maintained for the reasons of record, and the reasons above.

13. **(Prior Rejection- Maintained)** Claims 1, 2, 4, 9, 10, 12, 15, and 18 were rejected under 35 U.S.C. 103(a) as being unpatentable over Van Woensel et al. (U.S. 5,925,359).

The Applicant traverses the rejection on similar grounds as asserted with respect to the Wechter reference above. However, as with Wechter, the reference specifically indicates that either live (attenuated) or inactivated virus may be incorporated into the iscoms. Thus, the reference indicates that the live viruses may be so incorporated. The reference makes no indication that the viruses are of necessity killed by such an incorporation, and the Applicant has

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provided no evidence in support of this assertion. The rejection is therefore maintained for the reasons above, and the reasons of record.

14. **(Prior Rejection- Maintained)** Claims 5-8, 13, and 14 were rejected under 35 U.S.C. 103(a) as being unpatentable over Van Woensel et al. as applied to claims 1, 2, 4, 9, 10, 12, 15, and 18 above, and further in view of Cox et al. (WO 96/11711). The rejection is further extended to new claims 20-23 on the substantially the same grounds that the claims were rejected over Wechter in view of Morein and Cox above.

The Applicant traverses the rejection on the same basis asserted with respect to the rejection over Van Woensel above. The arguments are not found persuasive for the reasons above. The rejection is therefore maintained for the reasons above, and the reasons of record.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Conclusion

16. No claims are allowed.

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17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is (571)272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Zachariah Lucas/

Primary Examiner, Art Unit 1648